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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,628	10/06/2000	G. Grady McBride	5259-04700	1875

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PAUL D. YASGER
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents_Abbott_Park@abbott.com
Legal_Patents@abbott.com

Office Action Summary	Application No. 09/684,628	Applicant(s) MCBRIDE ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-78,80-84,86-98 and 286 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-78,80-84,86-98 and 286 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The indication of allowable subject matter in the Office action of February 18, 2005 is hereby withdrawn; and in response to the amendment of July 20, 2007, new grounds of rejection are presented below.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 97 and 98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not describe a system including, inter alia, first and second elongate members and a connector having first and second sections and a fastening system with a collet and a collar, where the length of the connector may be adjusted by bending the connector.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 91-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 91, the first and second

elongated members are said to be “coupled to bone,” where bone is an unpatentable part of the human body essentially claimed as structural part of the invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 70, 71, 74, 78, 86, and 88-90 rejected under 35 U.S.C. 102(b) as being anticipated by Drewry et al. (5,947,966). Drewry et al. disclose, at least in figures 1-5, 8, 9, 19, and 20; a connector including a body (e.g., 20, 40, or 150), first and second openings (e.g., 36) in the body, and a cam system (e.g., 16 or 41) positioned in a cam system opening (e.g., 35 or 44), where the system is configured to extend an engager (e.g., 38) into the first opening, where the longitudinal axis of the cam system is angled at an angle between about 40 deg. and about 90 deg. or at a non-perpendicular angle relative to a longitudinal axis of the body, where the cam system is positioned between the first and second openings of the body (see fig. 9), where the cam system opening is positioned so that the cam system is not located between the first and second openings (see fig. 3), where the connector includes a visual indicator that informs a user that the cam system is engaged (any surface feature of the body and/or the cam system

Art Unit: 3773

indicating the relative positions of these elements), where the body comprises first and second sections (e.g., 155, 162) and a fastener (e.g. 180) configured to inhibit movement of the first section relative to the second section, where the connector is a transverse connector of bone or spinal stabilization system.

8. Claims 70, 77, 80, and 81 are rejected under 35 U.S.C. 102(e) as being anticipated by Troxell et al. (6,283,967). Troxell et al. disclose, at least in figures 1-3; a connector including a body (10), first and second openings (at 106) in the body, and a cam system (94) positioned in a cam system opening (100), where the system is configured to extend an engager (102) into the first opening, where the longitudinal axis of the cam system is angled at an angle between about 40 deg. and about 90 deg. or about 60 deg and about 90 deg., where the longitudinal axis of the cam system is located substantially perpendicular to a longitudinal axis of the body, and where the rotation range of the cam system is limited (distal portion of 100).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 3773

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 72, 73, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drewry et al. (5,947,966). Drewry et al. disclose the invention substantially as claimed, but does not specifically disclose that a distance between a center of an elongated member (11 or 12) positioned in the first opening and a center of an elongated member positioned in the second opening is dimensioned as claimed. Nevertheless, it would have been a matter of obvious design choice to dimension the connector, so that the abovementioned distance is as claimed; since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

11. Claims 82-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Troxell et al. (6,283,967). Troxell et al. disclose the invention substantially as claimed, but do not specifically disclose that the rotation range of the cam system is as claimed. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to configure the cam system, so that it has a rotation range as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

12. Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drewry et al. (5,947,966) in view of Espy (2,719,042). Drewry et al. disclose the invention substantially as claimed. Drewry et al. disclose, at least in col. 5, lines 17-20; a drive

Art Unit: 3773

tool or a “conventional driving tool” that activates the cam system, but Drewry et al. do not disclose that the tool has handle providing a visual indicator that the cam system is engaged with an elongated member. Espy teaches, in figures 1 and 2, a conventional drive tool usable with the cam system of Drewry et al., where the tool includes a handle (10 or top portion of element 16) that can indicate the position of the cam system relative to the elongated member (i.e., the orientation of handle relative to the elongated member or other frame of reference would provide a visual indicator). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Espy, to include a drive tool having handle as claimed with the connector of Drewry et al. Such a handle would not only provide a visual indicator as claimed, it would allow improved grip of the drive tool and leverage for imparting any desired degree of torque to the cam system.

13. Claims 91-94 and 286 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allard et al. (5,676,664) in view of Drewry et al. (5,947,966). Allard et al. disclose the invention substantially as claimed. Allard et al. discloses a bone stabilization system or a transverse connector including first and second elongated members (50, 30) that can be coupled to bone by first and second fixation elements (38), and a connector comprising a first opening (in 52 or 32) configured to accept the first elongated member, the connector comprising first and second sections (14, 12), where a position of the first section is adjustable relative to the second section, where a fastening system comprising a collet (e.g., 66 or 90) and a collar (e.g., 68 or 92) inhibits movement of the first section relative to the second section, where the connector

includes an engagement system (in 52 or 32) configured to couple the connector to the second fixation element (via 50 or 30), and where the connector has a substantially fixed length (i.e., the length of element 22). However, Allard et al. do not disclose that the connector (at 52 or 32) and the engagement system (at 52 or 32) each include a cam system positioned in a cam system opening, where the connector includes an engager. Drewry et al. teach, for example, in figures 25 and 26, and in col. 2, lines 49-57; a cam system (241) including an engager (distal, conical end of 241) positionable in a cam system opening (225) of a connector or engagement system. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Drewry et al., to modify the connector or engagement system (at 52 or 32) of Allard et al., so that it has a cam system and cam system opening as claimed. A connector or engagement system with a cam system and engager would conveniently allow top-loading of the connector or engagement system over rods or elongated members, as well as top-tightening of the apparatus for stabilization of bone or the spine.

14. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allard et al. (5,676,664) in view of Drewry et al. (5,947,966), and further in view of Asher et al. (5,129,900). Allard et al. in view of Drewry et al. disclose the invention substantially as claimed, but do not disclose that the first and second elongated members (50 and 30 or Allard et al.) are each a unitary, bent, and contoured member. Asher et al. teach, at least in figure 2, and in col. 3, lines 7; elongated members (26) that are each a unitary, bent, and contoured member. It would have been obvious to one having ordinary skill in

Art Unit: 3773

the art at the time the invention was made, in view of Asher et al., to include unitary, bent, and contoured elongated members in the connector of Allard et al. in view of Drewry et al. Such a modification would allow the elongated members to be bent and oriented with respect to bone or the spine as desired.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

March 28, 2008